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January 16, 2018

By US mail and email at FOIARequest@psc.hhs.gov

Agency Chief FOIA Officer
U.S. Department of Health
and Human Services
Office of the Assistant Secretary
for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

FOIA APPEAL – Food and Drug Administration

Dear Sir or Ms.:

I hereby formally appeal denial of access to records, FDA No. 2016-5287.

I represent the Citizens Commission on Human Rights, on whose behalf I made a request pursuant to the Freedom of Information Act to the Food and Drug Administration in June 2016. That FOIA request has been the subject of delay and procrastination by the FDA and not acted upon within the statutory time period, as set forth below.

On June 21, 2016, a simple FOIA request was submitted to the FDA seeking solely, "Copies of communications between the FDA and MECTA." MECTA is a medical device manufacturer of electro-convulsive therapy devices, which are subject to the jurisdiction of the FDA. A copy is appended to this letter.

One year later, on June 14, 2017, the FDA's Center for Devices and Radiological Health FOIA division responded, through Latoye Lewis, Information Specialist, requesting confirmation that I still wanted the records requested. That communication, via email, stated "if you would like CDRH to continue processing your request we would need to know the type of communication records you are seeking (adverse events, compliance actions, approval correspondence, etc)." I responded:

> To assist you, I also specifically want all communications relating to reclassification of ECT devices, all communications regulating them or addressing their activities, affects, failure to report adverse events, failure to report claims against them for harms caused by the device. In short, as my FOIA Request stated, I want ALL communications with MECTA. FDA will know better than I how it categorizes all of their communications, so I have not limited the request to categories which I know.

Ms. Lewis responded the same day, stating:

> As your request is reaching the top of the queue, we reach out to make sure the information is still needed before we begin processing the request. Your request has not reached the top of the queue as of yet. However, I anticipate the search will begin with the next 2 to 4 weeks.

No assertion was made by CDRH that this simple Request was in any way complicated or "complex." Rather, Ms. Lewis stated the search would begin in 2-4 weeks (i.e., between June 29, 2017 and July 12, 2017 because, my request "is reaching the top of the queue.")

On July 11, 2017, I queried the progress of the processing of the Request. Ms. Lewis then represented that her June 14, 2017 estimate was accurate - that the processing would begin in 2-4 weeks (from June 14th).

On July 24, 2017, Ms. Lewis stated:

> Your request has begun processing. In order to obtain the records being sought my office has to reach out to other component offices with CDRH to conduct the search. The search has not been completed at this time. I estimate that your request will be closed within 4 to 8 weeks.

On August 14, 2017, in response to a further request for an update, Ms. Lewis provided further assurances that the processing of the FOIA Request was proceeding, stating:

> The time frame I recently provided you is still accurate (4 to 8 weeks). If you have any additional questions please let me know.

On September 21, 2017, I requested a further update, given that CDRH had missed several represented target dates to complete the processing of the Request. That communication to CDRH stated:

> Thank you for your email. But it doesn't take a year to conduct this simple search. It doesn't take months. It should take a few minutes. FDA is required by federal law to comply with the letter and intent of the FOIA. I understand that delays are inevitable and that there was an FOIA backlog. But I cannot help but conclude that the delay of my request is intentional, as the records I requested last year are relevant to ongoing matters, and I was apparently passed over in priority for other later FOIA requests. Can you please identify which divisions of CDRH are declining to provide responsive records, and the individuals in those sections responsible to comply?

By email dated September 27, 2017, Ms. Lewis responded to my suggestion that the FDA was intentionally delaying my request, by controverting all prior representations and stating that the FDA was removing my Request from the processing it was allegedly undergoing, and placing it on a slower track:

> The current processing time for most requests in the complex queue is 18 - 24 months. Due to the complexity of the subject matter of your request (per your email clarification on *6/14/17),* your request has been placed in the complex queue for processing. Your request requires multiple offices and locations to be searched for responsive records. We are processing your request as quickly as possible. Please be advised that we process requests in a first-in, first-out manner.
>
> There currently are 6 complex and voluminous requests ahead of your request in my queue. As of today, the estimated completion date for your request is March 31, 2018. This timing could change based on when I receive all responsive records and the volume of the records for my review.

Essentially the FDA email stated that rather than completing the processing it was already undergoing, as previously represented, the FDA was ceasing the processing of my Request with the stratagem of placing my Request into a "complex" queue, *behind* other requests which it viewed to be complex. FDA asserted this removal of my Request from processing and placing it in a slower "complex" queue, was based on my supposed clarification of the Request 3½ months earlier, and/or because it required multiple" offices in CDRH to search notwithstanding several assurances that all was on track. Such a response

manifests a lack of due diligence at best, and worse, constitutes a transparent endeavor to delay and avoid processing the Request.

Indeed, all correspondence with MECTA would have been collected in order to produce the Executive Summary regarding the classification of ECT devices, which the FDA released in 2010 and which was the subject of hearings in 2011. Presumably the FDA also collected the correspondence with MECTA in response to public objections at those hearings and in public submissions thereto. FDA requested MECTA produce all safety and efficacy information in 2010 and thereafter. In short, this FOIA request is simple. The agency's late-designation of it as "complex" is transparent.

I therefore wrote to the FDA and asked it to reverse this conduct, or that I would necessarily proceed with an administrative appeal. The FDA responded that such an act would cause the Request to be further delayed – thus threatening that the exercise of the right to appeal would be met with further unlawful delay as a punishment therefor.

Obviously the fact that "several offices" of one Division of the FDA must conduct a "search" for these very limited records, hardly makes the Request "complex." And, given the prior assurances that the searches were progressing more than 6 months ago, as well as the threat to further delay, the response appears to be disingenuous.

I accordingly submit this Administrative Appeal to the effective denial of my FOIA Request. Please cause the records at issue to be immediately processed and produced. Thank you.

Sincerely,

Kendrick Moxon

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June 21, 2016

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: FOIA Request Regarding Communications with MECTA Corporation

On behalf of my client, Citizens Commission on Human Rights, pursuant to the federal Freedom of Information Act I hereby formally request production of:

> Copies of all communications between the FDA and MECTA Corporation.

To aid you to locate responsive records, please be advised that for the past 30 or more years, MECTA has sought and received approval pursuant to section 510(k) for authority to market Electroconvulsive Therapy devices manufactured by MECTA. I seek all correspondence between MECTA and the FDA, dated from 2000 to the present.

I hereby authorize the expenditure of up to $150 for the search and duplication of the requested records. Please contact me if the estimate is higher than this amount. However, my client is a non-profit public benefit organization which will disseminate the information to the public when received, thus a fee waiver is requested.

Please contact me at the above listed email address and/or phone number with any questions.

Sincerely,

Kendrick Moxon